www.cdc.gov/niosh/topics/surveillance/

CoalWorkersHealthSurvProgram.html, via electronic transmission. Facilities must utilize a secure internet data transfer site specified by NIOSH. The transmitted spirometry data files must include a variable length record providing all parameters in the format, content, and data structure described by the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, see §37.97), or an alternate data file that is approved by NIOSH. If electronic transmission of spirometry results is not possible, for example if a facility's spirometer does not provide an approved electronic transfer of spirometry files, then the miner's Spirometry Results Form (Form CDC/NIOSH (M)2.17), available at http://www.cdc.gov/niosh/ topics/surveillance/ords/

CoalWorkersHealthSurvProgram.html, must be completed and submitted accompanied by image files documenting the flow-volume and volume time curves for each trial reported on the Results Form. Such facilities must also send a completed Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) and Spirometry Notification Form (Form CDC/NIOSH (M)2.16). Data submission to NIOSH by such a facility must be carried out as specified in the facility's approval.

(e) Confidentiality of spirometry examinations. Individual medical information and spirometry results are considered protected health information under HIPAA and may only be released as specified by HIPAA or to NIOSH as specified in §§ 37.93 and 37.96 of this subpart. Personally identifiable information in the possession of NIOSH will be released only with the written consent of the miner or, if the miner is deceased, the written consent of the miner's next of kin or legal representative. To provide on-site back-up and assure complete data transfer, facilities will retain the forms and results (in electronic or paper format) from a miner's examination until instruction has been received from NIOSH to delete the associated files and forms or, if this is not technologically feasible, render the data permanently inaccessible.

§ 37.97 Standards incorporated by reference.

- (a) Certain material is incorporated by reference into this subpart, Subpart—Spirometry Examinations, with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, NIOSH must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at NIOSH, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, 26505. To arrange for an inspection at NIOSH, call 304-285-5749. Copies are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http:// www.archives.gov/federal register/ code of federal regulations/ $ibv \overline{locations.html}$.
- (b) American Journal of Respiratory and Critical Care Medicine, American Thoracic Society (ATS), 25 Broadway, 18th Floor, New York, NY 10004. Phone: (800) 635–7181, extension 8065. Email: http://www.atsjournals.org/action/showHome:
- (1) Standardization of Spirometry; 1994 Update. Official Statement of the ATS, adopted November 11, 1994. American Journal of Respiratory and Critical Care Medicine 152(3):1107–1136, September 1995, into §37.95(b). This ATS Official Statement is also available at http://www.thoracic.org/statements/resources/archive/201.pdf.
- (2) Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting ("ATS Technical Standards: Spirometry in the Occupational Setting"). Redlich CA, Tarlo SM, Hankinson JL, Townsend MC, Eschenbacher WL, Von Essen SG, Sigsgaard T, and Weissman DN. American Journal of Respiratory and Critical Care Medicine 189(8):983–994, April 15, 2014, into §§37.92(b) and 37.96(a).
- (3) Spirometric Reference Values from a Sample of the General U.S. Population. Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine,

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159(1):179–187, January 1999, into § 37.92(b).

- (c) European Respiratory Journal, 442 Glossop Road, Sheffield, S10 2PX, UK. Phone: 44 114 267 28 60; Fax: 44 114 266 50 64. Email: info@ersj.org.uk. http://erj.ersjournals.com/.
- (1) Standardisation of Spirometry ("2005 ATS/ERS Standardisation of Spirometry"). ATS/ERS Task Force: Standardization of Lung Function Testing. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Crapo R, Enright P, van der Grinten CPM, Gustafsson P, Jensen R, Johnson DC, MacIntyre N, McKay R, Navajas D, Pedersen OF, Pellegrino R, Viegi G, and Wanger J. European Respiratory Journal 26(2):319-338, August 2005, into §§ 37.93(b); 37.95(b) and (c); and 37.96(d). The ATS/ERS Standardisation of Spirometry is also available on the ATS Web site at https://foundation.thoracic.org/statements/resources/pft/ PFT2.pdf.
- (2) Interpretative Strategies for Lung Function Tests ("ATS/ERS Interpretative Strategies for Lung Function Tests"). ATS/ERS Task Force: Standardisation of Lung Function Testing. Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R, Coates A, van der Grinten CPM, Gustafsson P, Hankinson J, Jensen R, Johnson DC, MacIntyre N, McKay R, Miller MR, Navajas D, Pedersen OF, and Wanger J. European Respiratory Journal 26(5):948-968, November 2005, into §37.96(a). The ATS/ ERS Standardisation of Lung Function Testing is also available on the ATS Web site at http://www.thoracic.org/statements/resources/pft/pft5.pdf.
- (3) Standardisation of Lung Function Testing, the Authors' Replies to Readers' Comments ("Standardisation of Lung Function Testing, Replies to Readers"). Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R. Coates A, Enright P, van der Grinten C, Gustafsson P, Jensen R, MacIntyre N, McKay RT, Pedersen OF, Pellegrino R, Viegi G, and Wanger J. European Respiratory Journal 36(6):1496-1498, December 2010, into§37.95(c). Standardisation of Lung Function Testing, Replies to Readers is also available on the ATS Web site at http://

www.thoracic.org/statements/resources/pft/clarification-12-2010.pdf.

Subpart—General Requirements

Source: 79 FR 45123, Aug. 4, 2014, unless otherwise noted.

§ 37.100 Coal mine operator plan for medical examinations.

- (a) Each coal mine operator must submit and receive NIOSH approval of a plan for the provision of chest radiographs, occupational histories, spirometry examinations, and respiratory assessments of miners, using the appropriate forms provided by NIOSH.
- (1) During the transition from August 1, 2014 until the time when spirometry facilities are approved by NIOSH, any person becoming a coal mine operator on or after August 1, 2014, or any coal mine operator without an approved plan as of that date must submit a plan within 60 days that provides for chest radiographs and occupational histories.
- (2) Coal mine operators with previously approved plans for only chest radiographs and occupational histories, or with plans developed pursuant to paragraph (a)(1) of this section, will be notified by MSHA when the plans must be amended to include spirometry examinations and respiratory assessments. Amendments must be submitted to NIOSH within 60 days of MSHA's notification.
- (b) The coal mine operator's plan must include:
- (1) The name, address, and telephone number of the operator(s) submitting the plan;
- (2) The name, MSHA identification number for respirable dust measurements, and address of the mine included in the plan;
- (3) The proposed beginning and ending date of the 6-month period(s) for voluntary radiography and spirometry examinations (see §37.3(a) and §37.92(a)), the estimated number of miners to be given or offered examinations during the 6-month period under the plan, and a roster specifying the names and current home mailing addresses of each miner covered by the plan;